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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,540	09/27/2000	Timothy W. King	121117-1000	6703

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/19/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,540

Applicant(s)

KING ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, Request for Continued Examination, and Preliminary Amendment A.

Response to Arguments

Applicant amended the claims to include a proviso against a second emulsification step. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13-18, and 23-36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,407, 609 to Tice *et al.*.

Tice *et al.* teach a method of encapsulating an agent. Tice *et al.* teach that a suitable wall forming material, such as a polymer, is first dissolved or otherwise dispersed in a solvent (c 3, l 50-52). The liquid or solid agent to be encapsulated is then dispersed or dissolved in the solvent containing the dissolved wall forming material (c 4, l 30-32). This mixture is then added to a continuous process medium to form microdroplets (c 5, l 50-52). The process medium is then

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mechanically agitated with devices such as homogenizers, propellers or the like (c 6, l 9-12).

Once the emulsion is formed, the process medium is transferred to an extraction medium so that the solvent can be removed from the microdroplets (c 6, l 23-27). Lastly, the microcapsules or microspheres are collected by centrifugation, filtration or the like (c 6, l 42-46). Tice *et al.* teach that the active can be selected from a large group of possible therapeutic agents, including peptides and proteins, such as LHRH, growth hormone, and others (c 4, l 65-66). Tice *et al.* teach that the solvent can be methylene chloride, chloroform, and others (c 3, l 53-63). Tice *et al.* teach that polyvinyl alcohol can be used as the processing medium (c 5, l 60).

These teachings anticipate the above listed claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice *et al.*, in view of US Patent 5,622,657 to Takada *et al.*.

Tice *et al.* are discussed above as teaching Applicant's claimed method for forming microspheres. Tice *et al.* do not teach that the bioactive substance is stabilized with a carrier protein, such as albumin.

Takada *et al.* disclose a microparticles preparation comprising microparticles of a polymer which contain a drug and are coated with a film agent. Takada *et al.* are relied upon for

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the teaching that albumin, as well as gelatin, are known in microparticle formulations as a drug stabilizer. Takada *et al.* teach that during the production of the microparticles, stabilizers, such as albumin, can be added to stabilize the drug.

One of ordinary skill in the art would have been motivated to use a stabilizer, such as albumin, in a microparticle formulation to stabilize the active agent. The motivation lies in the teachings of Takada *et al.*, where it discloses that albumin is known in microparticle formulation to stabilize active agents. The expected result would be a successful, stabilized microparticle formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tice *et al.* in view of Baker *et al.*.

Tice *et al.* are discussed above as teaching Applicant's claimed method for forming microspheres. Tice *et al.* do not teach that the polymeric substance is a combination of PLGA and PEG.

Baker *et al.* teach a method for distributing a therapeutic agent in encapsulated form. Baker is relied upon for teaching that both PLGA and PEG are known in the art to as polymeric materials suitable for forming microparticles (c 5, l 46-50).

One of ordinary skill in the art would have been motivated to use any well known wall forming material in a method to produce microparticles. The motivation lies in the teachings of Baker, which shows that both polyethylene glycol and PLGA are known encapsulating materials. The expected result would be a successful microparticle formulation. Therefore, this invention

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as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
May 14, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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